REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. EXAMINER INTERVIEW

Applicants thank Examiners Steadman and Woodward for the telephone interviews discussing the outstanding Office Action.

II. CLAIM STATUS & AMENDMENTS

Claims 1-13 and 15 are pending

Claims 1, 13 and 15-17 have been examined on the merits. Claims 2-12 are withdrawn as non-elected subject matter.

In item 5 on page 1 and in item 18 on page 13, it is indicated that claim 1 is allowed.

Claim 13 is amended to clarify that the transformed cells are cultured under suitable conditions for protein expression as disclosed at page 10, lines 13-21 of the specification.

Therefore, no new matter has been added by this amendment.

III. INDEFINITENESS REJECTION

Claim 13 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly incomplete for omitting essential method steps. In item 13 on page 4, it is indicated that the claims omit the step of culturing the host cell under conditions suitable for expression of the protein.

As noted above, the claim has been amended to include the step indicated as omitted by the Examiner. Thus, the indefiniteness rejection of claim 13 is untenable and should be withdrawn.

IV. ENABLEMENT REJECTION

Claims 13 and 15 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is only enabling for the polypeptide of SEQ ID NO:2 and a method for production thereof by culturing a host cell transformed with a vector comprising the nucleic acid of SEQ ID NO:1 or a nucleic acid encoding SEQ ID NO:2, and not for polypeptide variants encoded by nucleic acids that hybridize with SEQ ID NO:1 under the specifically recited stringent conditions. See item 13 on pages 4-12 of the Office Action.

On page 6 of the Office Action, it is indicated that claim 15 is so broad as to encompass a vast number of polypeptide variants having PF1022 synthetase activity. Specifically, it is indicated that the hybridization language encompasses numerous variants and it would take undue experimentation to produce and isolate such variants. On page 7, the Examiner contends that, aside from SEQ ID NO:2, there was no disclosure of polypeptides having PF1022 synthetase activity at the time of the claimed invention. On pages 8-9, it is indicated that the art is highly unpredictable with regard to altering the polypeptide of SEQ ID NO:2 with an expectation of obtaining a polypeptide having PF1022 activity. It is also indicated that the disclosure is limited to the single working example of SEQ ID NO:2 and a method of making this polypeptide having PF1022 activity.

This rejection is respectfully traversed.

It is respectfully submitted that the polypeptides encompassed by claims 13 and 15 do not include the vast number of polypeptide variants of SEQ ID NO:2 having PF1022 synthetase activity as asserted on page 6 of the Office Action.

As discussed in the prior response, the claims were amended to be directed to an isolated polypeptide having PF1022 activity and a method of making such, wherein the polypeptide is encoded by a nucleotide sequence that hybridizes under stringent conditions with the nucleotide sequence of SEQ ID NO: 1. Moreover, the claims clearly recite the specific stringent conditions as set forth on page 6, lines 11-16 of the disclosure. It is respectfully submitted that the

polypeptides encompassed by claims 13 and 15 do not include a vast number of polypeptide variants of SEQ ID NO:2 having PF1022 synthetase activity.

In this regard, kindly take note of Examples 9 and 10 of the USPTO's Written Description Examination Guidelines, 66 Fed. Reg. 1099 (Jan. 5, 2001), copies of which are attached. Although the Guidelines deal with written description issues, as opposed to enablement, the Examples and analysis therein are instructive for the instant case. For instance, in Example 9, the claim is drawn to a genus of nucleic acids which hybridize under stringent conditions to a known DNA sequence, SEQ ID NO: 1, and encode a protein with a specific activity. There is a single species disclosed, i.e., SEQ ID NO: 1. Regarding the genus, it is clearly indicated that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent conditions set forth in the claims yield structurally similar DNAs."

Likewise, in Example 10, the claims are drawn to a process for producing an isolated DNA that hybridizes under stringent conditions to a known sequence and to the DNA sequences which hybridize to the known sequence. Again, the PTO recognized that there is no substantial variation within the genus because of the stringency of hybridization yields structurally similar molecules.

Kindly also take note of the following decisions Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 20002) and Ex parte Herrmann, No. 2002-1630 (BPAI 2003), copies of which decisions are enclosed.

In Enzo, the Federal Circuit held that "[a]dequate written description may be present for a genus of nucleic acids based on their hybridization properties, 'if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar.'" Enzo, 296 F3d. at 1327, 63 USPQ2d at 1615.

The Board in Herrmann dealt with similar issues for a claim directed to a genus of DNA that hybridize under stringent conditions. The Board found that polynucleotides encompassed by the claims directed to DNA that hybridize under stringent conditions to known DNA "do not

include the 'potentially infinite number of variants'" as posited by the Examiner. Herrmann, page 17.

Thus, in view of the above, it is respectfully submitted that, contrary to the position taken in the instant Office Action, the PTO correctly recognizes that there is no substantial variation within a claimed genus of sequences because of the stringency of hybridization yields structurally similar molecules.

In the instant case, the claims are limited by hybridization under stringent conditions. The set of sequences that hybridizes is limited to those sequences that form the requisite number of base pairs over the hybridizing sequence. As recognized by the PTO, hybridization under the specified stringent conditions of the claims require that the nucleotide sequence be structurally similar to the nucleotide sequence of SEQ ID NO:1. By using stringent conditions, the "vast number" of variant polynucleotides would be excluded from the claims. In fact, most variants would simply not hybridize to SEQ ID NO:1 under such conditions. Accordingly, the claims are of a much narrower scope than, for example, hybridization under non-stringent conditions. Thus, in contrast to the position taken in the Action, the polypeptides encompassed by claims 13 and 15 do not include a vast number of polypeptide variants of SEQ ID NO:2 having PF1022 synthetase activity.

Furthermore, it is well established that the test of enablement is whether one reasonably skilled in the art could make or use the invention based on the disclosure in the specification coupled with the knowledge in the art without undue experimentation. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. The test is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. In fact, the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. See M.P.E.P. § 2164.01.

As discussed in the previous response, hybridization techniques and procedures are common and well known in the biotech industry. As such, it would only require routine experimentation for the skilled artisan to isolate DNA that hybridizes under stringent conditions to SEQ ID NO:1 and to produce the polypeptide encoded by this DNA. Likewise, it would only require routine experimentation to then test the polypeptide for the PF1022, cyclic depsipeptide synthetase activity.

Accordingly, it is respectfully submitted that it would not take undue experimentation to utilize the routine techniques disclosed in the specification and known in the art to express the limited number of DNA that hybridize under stringent conditions to SEQ ID NO:1 and to test the limited number of polypeptides encoded by these nucleotides for the requisite PF1022 activity.

Furthermore, it is respectfully submitted that this rejection conflicts with accepted practice at the PTO regarding claim language and hybridization under stringent conditions. The attached results of an online search of the PTO database for claim language containing "stringent conditions" show that the PTO has allowed over a thousand patents with such claim language. While it is acknowledged that patentability must determined on a case-by-case basis, the results of the online search demonstrate that the PTO has long accepted such language in the claims. Thus, it appears that the rejection conflicts with a well accepted practice at the PTO.

Therefore, the scope of enablement rejection under 35 U.S.C. § 112, first paragraph, is untenable and should not be applied to amended claims 13 and 15.

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Therefore, the scope of enablement rejection under 35 U.S.C. § 112, first paragraph, is untenable and should not be applied to amended claims 13 and 15.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below if he has any suggestions to expedite allowance.

Respectfully submitted,

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ATTACHMENTS:

1. Examples 9 and 10 of the USPTO's Written Description Examination Guidelines, 66 Fed. Reg. 1099 (Jan. 5, 2001);

2. Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 20002);

3. Ex parte Herrmann, No. 2002-1630 (BPAI 2003).

4. Online search of the PTO database for claim language containing "stringent conditions."